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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/574,124	04/23/2007	Harry J. Klee	UF.386CXC1	5548

23557 7590 05/14/2010
SALIWANCHIK LLOYD & SALIWANCHIK
A PROFESSIONAL ASSOCIATION
PO Box 142950
GAINESVILLE, FL 32614

EXAMINER

KALLIS, RUSSELL

ART UNIT	PAPER NUMBER
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1638

NOTIFICATION DATE	DELIVERY MODE
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05/14/2010

ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

euspto@slspatents.com

Office Action Summary	Application No. 10/574,124	Applicant(s) KLEE ET AL.	
	Examiner RUSSELL KALLIS	Art Unit 1638	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 09 February 2010.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-10, 13, 14, 18, 34-36, 47, 58 and 68 is/are pending in the application.
- 4a) Of the above claim(s) 1-10, 13, 14 and 68 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 18, 34-36, 47 and 58 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 31 March 2006 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Election/Restrictions

Applicant's election without traverse of Group VIII, claims 18, 34-36, 47 and 58 in the reply filed on 2/09/2010 is acknowledged.

Claims 1-10, 14, 18, 34-36, 47, 58 and 68 are pending. 1-10, 14, and 68 are withdrawn. Claims 18, 34-36, 47, 58 are examined.

Sequence information

The sequence listings both paper and electronic version indicate that the species source for SEQ ID NO: 8 encoding SEQ ID NO: 9 is *L. esculentum*. However, the specification indicates that the species source for SEQ ID NO: 8 encoding SEQ ID NO: 9 is *L. pennellii*. Clarification is requested.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Written Description

Claims are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The claims are broadly drawn to a polynucleotide construct comprising a plant phenylalanine decarboxylase enzyme coding sequence, expression constructs thereof,

cells and a plant transformed therewith, and a method thereof for increasing the flavor or fragrance in a plant.

Applicants describe SEQ ID NO: 4, 6 and 8 encoding SEQ ID NO; 5, 7 and 9 respectively from tomato species encoding phenylalanine decarboxylase enzymes.

Applicants do not describe any conserved features required for activity of the broadly claimed genus of phenylalanine decarboxylases or a representative number of sequences of phenylalanine decarboxylase enzymes and their respective coding sequence from the broadly claimed genus of plant phenylalanine decarboxylase sequences.

The Federal Circuit has recently clarified the application of the written description requirement to inventions in the field of biotechnology. The court stated that, “A description of a genus of cDNAs may be achieved by means of a recitation of a representative number of cDNAs, defined by nucleotide sequence, falling within the scope of the genus or of a recitation of structural features common to members of the genus, which features constitute a substantial portion of the genus.” *See University of California v. Eli Lilly and Co.*, 119 F.3d 1559; 43 USPQ2d 1398, 1406 (Fed. Cir. 1997).

Applicants fail to describe a representative number of phenylalanine decarboxylase enzymes sequences. Applicants only describe SEQ ID NO: 4, 6 and 8 encoding SEQ ID NO; 5, 7 and 9 respectively from tomato species encoding phenylalanine decarboxylase enzymes. Furthermore, Applicants fail to describe structural features common to members of the claimed genus of phenylalanine decarboxylase enzymes sequences. Hence, Applicants fail to meet either prong of the two-prong test set forth by *Eli Lilly*. Furthermore, given the lack of description of the necessary elements essential for xxx, it remains unclear what features identify a

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phenylalanine decarboxylase enzyme. Since the genus of phenylalanine decarboxylase enzymes sequences has not been described by specific structural features, the specification fails to provide an adequate written description to support the breadth of the claims.

Enablement

Claims 18, 34-36, 48 and 58 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for SEQ ID NO: 4, 6 and 8 encoding SEQ ID NO; 5, 7 and 9 respectively from tomato species encoding phenylalanine decarboxylase enzymes, expression constructs thereof, cells and a plant transformed therewith, and a method thereof for increasing the flavor or fragrance in a plant, does not reasonably provide enablement for any other phenylalanine decarboxylase sequence from plants other than SEQ ID NO: 4, 6 and 8 encoding SEQ ID NO; 5, 7 and 9 respectively from tomato species for use in altering flavor or fragrance in plants transformed therewith. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to x the invention commensurate in scope with these claims.

The claimed invention is not supported by an enabling disclosure taking into account the *Wands* factors. *In re Wands*, 858/F.2d 731, 8 USPQ2d 1400 (Fed. Cir. 1988). *In re Wands* lists a number of factors for determining whether or not undue experimentation would be required by one skilled in the art to make and/or use the invention. These factors are: the quantity of experimentation necessary, the amount of direction or guidance presented, the presence or absence of working examples of the

invention, the nature of the invention, the state of the prior art, the relative skill of those in the art, the predictability or unpredictability of the art, and the breadth of the claim.

The claims are broadly drawn to a polynucleotide construct comprising a plant phenylalanine decarboxylase enzyme coding sequence, expression constructs thereof, cells and a plant transformed therewith, and a method thereof for increasing the flavor or fragrance in a plant.

Applicants teach SEQ ID NO: 4, 6 and 8 encoding SEQ ID NO; 5, 7 and 9 respectively from tomato species encoding phenylalanine decarboxylase enzymes.

Applicants do not teach any other phenylalanine decarboxylase or any plants transformed with any phenylalanine decarboxylase sequence from any source having any altered flavor or aromatic qualities.

The state-of-the-art is such that one of skill in the art cannot reasonably predict any aromatic compound produced from a phenylalanine decarboxylase. Clearly only a phenylalanine derived aromatic could be produced from a phenylalanine aromatic decarboxylase (see Abstract of Tieman *et al.* Proc Natl Acad Sci U S A. 2006 May 23; 103(21): 8287–8292).

Given the lack of guidance in the instant specification, undue trial and error experimentation would be required for one of ordinary skill in the art to isolate and test a myriad of non-exemplified putative phenylalanine decarboxylase sequences isolated from a multitude of plant species and tested for flavor and aromatic altering ability in a host of non-exemplified plant species.

Therefore, given the breadth of the claims; the lack of guidance and working examples; the unpredictability in the art; and the state-of-the-art as discussed above,

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undue experimentation would be required to practice the claimed invention, and therefore the invention is not enabled throughout the broad scope of the claims.

All claims are rejected.

Claims 18, 34-36, 48 and 58 are deemed free of the prior art given the failure of the prior art to teach or reasonably suggest a polynucleotide construct comprising a plant phenylalanine decarboxylase enzyme coding sequence, expression constructs thereof, cells and a plant transformed therewith, and a method thereof for increasing the flavor or fragrance in a plant.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to RUSSELL KALLIS whose telephone number is (571)272-0798. The examiner can normally be reached on M-F 8:30-5.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anne Marie Grunberg can be reached on (571) 272-0975. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Russell Kallis/
Primary Examiner, Art Unit 1638
May 10, 2010